

Louisville Orthopaedic Clinic

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TOTAL JOINT REPLACEMENT
ARTHROSCOPY OF THE KNEE AND SHOULDER
SPECIALTY SURGERY OF THE SPINE
ATHLETIC INJURIES
FOOT AND ANKLE SURGERY

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 97N-484S

To Whom It May Concern:

I wish to express the following concerns. As a practicing spine surgeon for over twenty years, I am concerned about plans to change allograft materials so that they would be classified as medical devices. Over the last twenty years we have all used allograft bone as substitutes. In years past we had to fashion pieces of allograft bone to fit the purposes in which we needed them, such as anterior cervical or anterior lumbar fusions. Now, as a convenience to surgeons, the bone providers often pre-cut the bones into shapes that are easier, therefore serving the patients and society by cutting down on time required in the operating room to shape a piece of bone. Often times we still need to reshape even some of the allografts that we receive at this time, but certainly it has been a great service to have pieces of allograft bone readily available for us to use in the operating room. In as much as this has been a practice that has been going on even before the time I started my spine practice, it would seem impractical to add allograft bone pieces for use in the spine to the classification of medical devices. I would urge you to reconsider this proposition.

Sincerely,

Thomas R. Lehmann, M.D.

TRL/pn

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